



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

**WARNING LETTER
NWE-10-99W**

February 19, 1999

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Larken Walker
Medical Director
Lakes Region General Hospital
80 Highland Street
Laconia, NH 03246

Dear Dr. Walker:

An inspection of your blood bank facility on Highland Street in Laconia NH, 03246 was performed on February 5, 1999 by the Food and Drug Administration.

The inspection revealed that during the period of January 1998 to the present, your facility shipped 14 units of unlicensed autologous blood, in interstate commerce, in violation of Section 351 of the Public Health Service Act [42 U.S.C. 262(a)].

The above identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility as Medical Director to assure that your establishment is in compliance with all requirements of the Federal regulations.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violation and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

I am also enclosing a FDA 483, List of Observations, that was presented to Paula McDonald, Blood Bank Supervisor, at the conclusion of the inspection for your information.

Your response should be sent to Karen N. Archdeacon, Compliance Officer, United States Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have any further questions, please contact Ms. Archdeacon at 781-279-1675, Extension 113.

Sincerely,

A handwritten signature in cursive script, appearing to read "John Marzilli".

John Marzilli
District Director
New England District Office

cc: Paula McDonald
Blood Bank Supervisor
Lakes Region General Hospital
Highland Street
Laconia, NH 03246